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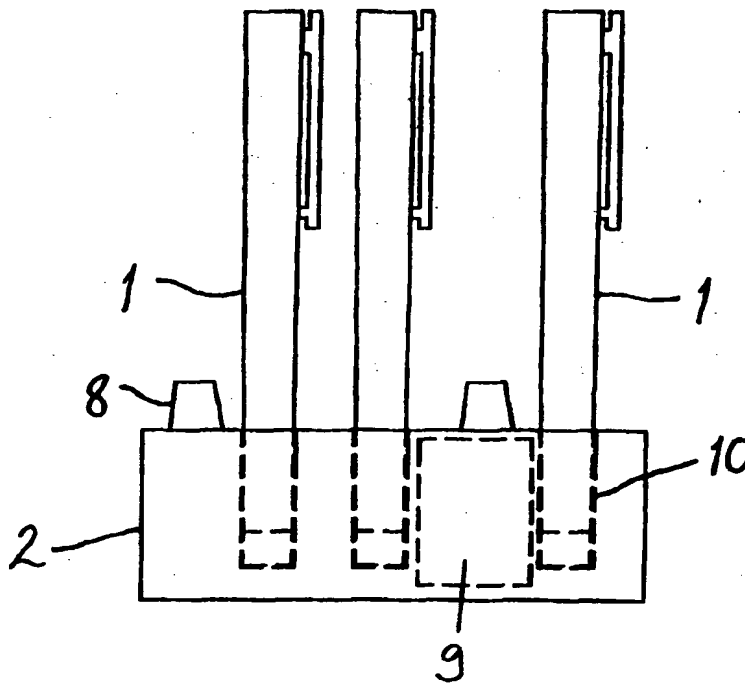
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**(54) Title:** DEVICE AND METHOD FOR INDICATING AN EVENT OF ADMINISTRATION

**(57) Abstract**

A device for indicating an event of administration is equipped with an indicator for registering an event of administration of a usually regularly administrable medicament. The indicating device (2) comprises a detector means (7) which is arranged to detect the mechanical movement of a medicament dosage unit (1) taking place in connection with an event of administration. The indicating device (2) comprises a registration means which is arranged to register information about the event of administration in the indicating device (2). The indicating device is a separate unit which can be attached to the medicament dosage unit (1) or in which the medicament dosage unit can be placed, and it can be used for example for monitoring the dosage of insulin in the treatment of diabetes.



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## Device and method for indicating an event of administration

5 The invention relates to a device for indicating an event of administration, with an indicator for registering an event of administration of a medicament that should be administered usually regularly. The invention relates also to a method for indicating such administration.

10 It is known to use various medicament containers with alarm systems based on timers for drug doses which are to be taken at intervals and are usually in the form of pills, tablets, or corresponding doses to be taken orally. For example, the application publication GB-2 179 919 discloses a medicament container which gives an alarm that can be turned off only by opening the container. Such a container can also  
15 contain a syringe or an ampoule. The application publication FR-2 666 225, in turn, discloses an alarm system for a medicament container equipped with compartments for pills, tablets or corresponding orally administered doses, each compartment having a separate lid and being provided with a separate alarm. The alarm is turned off automatically within 15 seconds, and consequently no information is left in the  
20 container, whether the dose has been taken or not.

For doses injected with electrically operated syringes, there are systems integrated in the syringe, coupled with the electronics of the  
25 syringe and used for controlling the administration of the doses. For example, US patent 4 417 889 discloses a system for preventing an extra dose integrated in the syringe, to prevent the use of the syringe a second time within a certain time interval after taking the dose, *i.e.* there is a kind of time lock. It is the fact that the syringe is operated with  
30 an electric motor that the detection of the administration and data storage is based on. US Patent 4 950 245 discloses a syringe intended for the use of a person having diabetes, an "injection pen", which can be used to administer a predetermined dose of insulin. The syringe has an integrated system with a sensor monitoring the progression of a  
35 pump rod inside the syringe and giving information to an electronic control unit for administering a correct dosage at the time of injection. In this syringe, the only alarm is an indication on the emptying of the reservoir to be expected.

Up to date, there has been no detector device or detection method that could be applied in a variety of syringes for controlling an event of administration. For example, diabetics must take a dose at regular intervals. Thus, it may remain uncertain whether a dose was really  
5 taken. For example, the most common injection pens are of the type that a dose is administered by setting a push button back and pressing it at the time of injection, wherein it moves a piston in a medicament container forward the set distance. The same problem occurs when  
10 different types of doses are taken in a regimen, for example within a day, whereby it is difficult to keep a register on the doses administered.

It is an aim of the invention to present a device, whereby the event of administering a dose can be detected in a reliable manner. For achieving the aim, the device according to the invention is primarily characterized in that it comprises a detector arranged to detect the mechanical  
15 movement of the dosage unit of medicament in connection with an event of administration. This movement can be the movement of a piston in the dosage unit or a part kinetically connected with it, or the release of the dosage unit from a support reserved for it.  
20

It is also an aim of the invention to present a method for detecting an event of administration. For achieving this aim, the method is primarily characterized in that the dosage unit is equipped with a separate,  
25 detachable indicating device, and when administering the dose, a specific detector means belonging to the indicating device is used to detect a mechanical movement, the event being automatically registered from the detector means in a memory.

30 By means of the invention, it is possible to create a completely novel regimen e.g. for the treatment of diabetes, which is not previously known and which can be easily implemented by the equipment available. Consequently, no structural changes need to be made in the injection pen itself, and it is possible to use ordinary injection pens in  
35 the market, which do not have the memory function in question as such. Moreover, the invention does not require the use of injection pens based on electrical operation, as presented in the patents US-4 417 889 and US-4 950 246, but it can be used in purely mechanical

injection pens in which the administration is effected by a movement effected manually.

5 In the following, the invention will be described in more detail with reference to the appended drawings, in which

- Fig. 1 is a schematic view showing the principle of a first embodiment of the invention in connection with an injection pen,
- 10 Fig. 2 is a side view on the first embodiment of the invention in connection with an injection pen when assembled,
- Fig. 3 shows the embodiment of Fig. 2 seen from a direction perpendicular to the direction of Fig. 2,
- 15 Fig. 4 shows the first embodiment in an end view seen from the direction of arrow IV,
- Fig. 5 is a side view on a second embodiment of the invention containing several dosage units,
- 20 Fig. 6 shows the embodiment of Fig. 5 seen from above,
- Fig. 7 illustrates the use of the embodiment of Figs. 5 and 6,
- 25 Fig. 8 shows another alternative of the embodiment of Figs. 2 to 4,
- 
- Fig. 9 shows another alternative of the embodiment of Figs. 5 and 6, and
- 30 Figs. 10 and 11 show further embodiments of the invention.

35 Figure 1 shows a normal injection pen 1 and an indicating device 2 to be placed as a separate piece around it. The indicating device can have e.g. a sleeve-like or corresponding structure so that it can be fixed to an ordinary injection pen without making changes in the structure of the latter. For example, it can be pushed in the axial direction at the rear end of the injection pen around the same (arrow). Similarly, it can

be equipped with a separate push-button piece 3 which can be fixed firmly around the normal push-button at the rear end of the injection pen.

5 Figures 2 to 4 show a combination of the indicating device 2 and the injection pen in assembled state. The indicating device 2 surrounds the upper end of the injection pen underneath the press 3. The indicating device 2 comprises a battery 4 and a pair of indicators 5a, 5b. The first indicator 5a is arranged to indicate when it is time to administer a dose.  
10 The device has also a means 7 for detecting a movement in connection with administering the dose, in this case the movement of a part moving with respect to the body of the injection pen, such as the push-button or a piston or another injection means and/or parts kinetically connected with the same. In the embodiment of Figs. 1 and 2, this is accomplished  
15 in a way that to the push-button 3, which has been set back and pushes a piston forward by means of a piston rod, is attached a part 6 which is drawn back with the setting movement and presses a micro-switch present in the indicating device 2, acting as said detector means 7, during the pushing movement. The part 6 moving together with the  
20 movement of the piston can be *e.g.* a tube-like piece which is received in a space reserved for it in the body of the indicating device 2 and which can be of a transparent material. In general, it is possible to use the movement of any part of the injection pen, which results in or which is a sign of administration of a medicament in the body.

25

When the movement of the piston is recognized in the above-described manner, the first indicator 5a is shifted into a state in which it reports that a dose was administered, *i.e.* the alarm stops. At the same time, information on the administration of the dose is stored in the device 1,  
30 and if one attempts to set the injection pen again for administration within a certain time from this event, the second indicator 5b of the indicator pair gives a warning.

35

It is also possible that, depending on the capacity of the power supply, such as a battery, the second indicator is turned on for a certain time period from the administration of the dose or until the next alarm is given. Thus, there is always information available on whether the previous dose was taken.

- The indicators 5a, 5b of the indicator pair can be e.g. visual indicators, such as indicator lights. The indicator lights can be realized in practice with LED's. The indicator lights are preferably of different colours, e.g. one green and the other red. At the same time with the operation of either or both of the indicators, an acoustic indicator can be arranged to give a sound signal, e.g. a suitable buzzer. This acoustic indicator is schematically indicated with the reference number 5c.
- 10 The indicating device 2 is also equipped with a setting switch 8, which can be used to select the alarm time corresponding to the dosage intervals. Similarly, it is provided with a window 17, through which the dosage scale in the body of the injection pen can be seen.
- 15 Figures 3 and 4 also show an electronics part 9 arranged on one side of the device 2 and also equipped with a space for a battery. The electronics part contains the couplings to the detector means 7, the memory functions required for registering the event, and the circuits required for the control of the alarms and the indicators.
- 20 Figures 5 to 7 and 9 show another indicating device 2 applying the same inventive idea. Also in this case, the indicating device 2 is a piece separate from the injection pen, and in this case it forms a stand for two or more injection pens 1. The purpose of the stand is to control and monitor the administration of several doses to be taken during the day.
- 25 To each injection pen 1, there is allotted a time of the day in the memory of the device telling when the injection should be taken. When it is the time to administer a dose from the pen, a visual indicator by the pen shows that the dose should be taken from the pen in question.
- 30 Also, an acoustic alarm is given. When the dose has been taken from the pen, the visual indicator by the pen remains, for a given time, for example until the beginning of the standby time of the same pen, in a state that shows that the dose has already been taken from the pen. This is indicated advantageously with an illuminated colour that can be easily detected. The indicator for the pen showing that a dose should be administered and the indicator showing that the dose has been taken can be different indicators which are turned "on" and "off". It is, of course, possible to use physically the same indicator which changes its
- 35

state, e.g. colour, according to the state of the pen in question. The operating principle is the same for each injection pen 1 to be monitored in the stand. The injection pens can be different in that they contain medicaments which act differently and which each should be administered at a certain time of a day. In the treatment of diabetes, the pens may contain different types of insulin.

The stand shown in Fig. 5 has vertical recesses 10 for placing injection pens in an erected position in the stand. The main principle of operation is the same as in the embodiment of Figs. 1 to 3, and it is best illustrated in Fig. 6. Each injection pen 1 is allotted an indicator pair 5a, 5b of its own. The device is arranged to alarm in a certain order, wherein the first indicator 5a of the respective injection pen alarms that it is time to administer a dose from the injection pen in question. The indicating device 2 detects the removal of this injection pen 1 from the stand by an arrangement where it has a means 7 detecting the movement of the injection pen away from the stand in a suitable way. Also in this case it is possible to use a suitable micro-switch operating on the contact principle, e.g. a switch placed on the bottom of the respective recess 10. When the sensor has detected the removal of the injection pen 1, the state of the first, alarming indicator 5a is reset. At the same time, the second indicator 5b is shifted to a state in which it indicates that the dose has been administered. For example, it is possible to use visual indicators, such as indicator lights. The light of the first indicator 5a can be turned off and the light of the second indicator 5b can be lit at the same time as a sign of removal of the injection pen. This can be realized in practice with LED's in the same way as in the embodiment of Figs. 1 and 2.

Furthermore, the device 2 has, e.g. by the recesses 10 for receiving the injection pens, similar alarm setting switches 8 as described above, one for each injection pen 1. These can also be used to set the suitable time intervals for example in a way that one switch is used to set the time telling at what time of the day the alarm is to be given, and the next switches can be used to set the dosage intervals, i.e. the time to the next alarm.



The figure shows a stand for five injection pens corresponding to five times of administration during a day. If there are fewer times of administration, the last space or spaces in the stand can be simply left empty.

- 5 Furthermore, Fig. 6 shows a separate indicator panel 12 coupled to the stand with a connection cable 11 and equipped with indicator pairs 5a, 5b operating in a way identical with the indicator pairs in the stand but provided also with a supplementary acoustic indicator 5c, such as a  
10 buzzer, common to all the indicators. Furthermore, the device comprises a mains transformer 13, a "power on" indicator 14 in the indicator panel, as well as a main switch 15 which is in the stand but which may also be in the indicator panel 12.

- 15 Figure 7 illustrates a way of using the device of Figs. 4 and 5. The injection pens 1 can be in a stand at a temperature suitable for them, for example in a refrigerator 16. The indicator panel can be brought with the connecting cable outside the refrigerator or a corresponding space, in which it reports the situation continuously. Thus, the administration situation can be monitored continuously, and the doses are kept at a  
20 lower temperature suitable for them. A refrigerator is not necessary if allowed by the indoor temperature or the stability of the medicament to be administered. In this case, there is no need for a separate panel brought outside the refrigerator either, but all the functions can be contained in the same device body. On the other hand, a separate  
25 indicator panel equipped with a connection cable may be useful in situations in which it is desirable to have the indicators in a visible place, even if the actual stand is not kept in a closed place.

- 30 The injection pens kept in the stand may still have their own indicating devices 2 according to Figs. 1 to 4, wherein it is possible to register both the removal of the injection pen from the stand and the administration of the dose from this injection pen.

- 35 Figure 8 shows another indicating device which is also suitable for use with a pen-type injection means. The device can be used to set a maximum of two injection times, which can give the alarm according to the need. A setting switch 8 is used to set the alarm times and to reset both timings. When the switch is pressed down a first time at the time

of the day when the first dose should be administered, the device beeps once with a buzzer 5c as a sign that the first alarm time is set. When the switch is pressed down again at a second time of day, this time of day is set as the second alarm time, and the device beeps twice  
5 as a sign of this. If the switch is pressed after this, the device beeps three times as a sign that both the alarm times are already set. If the switch is pressed continuously for a certain time, e.g. for at least 3 seconds, both of the alarm times are reset. The device beeps in this event five times and returns to its initial state. Thus, the setting switch 8  
10 is a simple one acting on pushing principle, and the timer of the device registers as the alarm time the time of day when the switch is pressed.

The detector means 7 is a micro-switch detecting the movement of the piston in the injection pen, i.e. the loading and administration of an  
15 injection. The micro-switch projects out from the end of the device 2, and a push-button at the end of the pen, which may be an extension piece arranged around the push-button of a commercial pen according to Fig. 1, presses the switch down in the normal position. When the pen is set for administration, the push-button is moved back and it releases  
20 the switch, and when the injection is administered after the setting, the push-button presses the micro-switch down again.

Each timing has a standby time which starts an hour before the alarm time and ends two hours after it. When the time to administer the dose  
25 comes up, the device beeps four times with the buzzer 5c. If the dose is administered not earlier than one hour before the selected alarm time, an alarm is unnecessary and will not be given. If the injection pen is loaded again (that is, at least a second time) within the standby state of the dose, the device gives three sound signals with the buzzer 5c,  
30 thereby warning from taking the same injection twice. At the same time, a visual indicator, e.g. the indicator light 5, flashes at the pace of the sound signal. This warning signal will not be given at other times, so that e.g. the insulin container can be changed at that time without an alarm.

35 The device registers the administration of a dose, when the push-button has been set backwards and it has returned forward, i.e. the micro-switch has returned to the initial state. For giving a warning

against a double injection, the setting of the push-button backwards will be sufficient.

- 5 The device can remind of administering the dose with the same alarm if the administration of the dose has not been registered within a certain time. The reminder can be repeated at given time intervals.

The following is a summary of the sound signals of the device:

1 Beep	Alarm time 1 set
2 Beeps	Alarm time 2 set
3 Beeps - If the indicator light flashes	Warning sound signal (wrong operation) Warning against double injection
4 Beeps	Alarm on injection
5 Beeps	Resetting of both alarm times

10

- Figure 9 shows an indicating device 2 intended for several dosage units 1. By pressing dosage unit specific setting switches 8, it is possible to set the alarm times and to reset the timings according to the same principle as in the device of Fig. 8. When the switch is pressed down (e.g. with a pointed tool, such as a pen) a first time, the device beeps once with the buzzer 5c as a sign that the alarm time is set. If the switch is pressed again, the device beeps four times as a sign that the alarm time is already set (error signal). By pressing the switch down continuously for a certain time, e.g. at least 3 seconds, said alarm time is reset. The device beeps five times and switches off the alarm of that injection pen whose setting switch 8 was pressed.
- 15
- 20

- Each timing has a standby time which starts one hour before the alarm time and ends three hours after that. During the standby time, the administration of the injection is being monitored. When the set alarm time is up, the device alarms with a sound signal and a green light is lit at the correct injection pen. The green light can be lit already when the standby time begins before the actual alarm. The detector 7 in the stand of injection pens detects that the injection pen is lifted from the stand, i.e. an injection is administered. When the pen is lifted at the right time, the green signal light is turned off and the red signal light is
- 25
- 30

turned on at the pen in question to remind that the injection has been taken. The red signal light is turned off only one hour before the alarm time of the same pen (when it is already allowed to administer a new injection). If the injection pen is lifted at the earliest one hour before the selected alarm time, the alarm is not necessary and is not given. If the injection pen is lifted again (*i.e.* at least a second time) within the standby time, the device gives eight quick sound signals, thereby warning to take the same injection twice. This signal is not given at any other time, so that *e.g.* the insulin container can be exchanged during that time without causing an alarm. After lifting the pen, there is a short delay (*ca.* 3 to 6 seconds), during which time the pen can still be put down if one *e.g.* notices that a wrong pen has been lifted. This delay time is set so that it is in no way possible to administer an injection during that time, *i.e.* the detection of returning the pen within a certain maximum time will not register a dose as having been administered. The device may remind of administering a dose with the same alarm if an administration is not registered within a certain time, *e.g.* in four minutes. The reminder may be repeated at certain intervals. The following is a summary of the sound and light signals of the device:

1 long beep	Alarm time of desired pen set
4 beeps	Error signal (wrong operation)
8 beeps	Warning to avoid double injection
4 x 4 beeps	Alarm to take an injection
5 slow beeps	Resetting of desired alarm time
Red signal light	Do not take an injection from this pen
Green signal light	You can take an injection from this pen

In the alternatives of Figs. 5 to 7 and 9, there can be also a special alarm function, that is, if the injection pen has not been removed from the stand within a certain time, *e.g.* during the predetermined standby time, a special alarm is given that is different from the alarms of the indicators 5a and 5b. Moreover, such a special alarm can be triggered first after two injection pens intended to be used in succession have not been removed during the respective times. The alarm can be given as a remote alarm outside the home of the user via a fixed telephone network or by using wireless telecommunication, such as GSM technol-

ogy. Visually, this can be indicated as a special signal in the device, e.g. both of the lights are turned off.

5 The detector means 7 can be arranged to operate by the contact principle, such as micro-switches, but it is also possible to use contactless movement sensors, such as optical or magnetic movement sensors, whereby it may be necessary to provide the part which moves in relation to another part in connection with the operation of administering a dose with a corresponding element, such as a ferrite or Hall element  
10 or an IR transmitter and receiver.

The embodiment of Figs. 5 to 7 and 9 can also be used for monitoring the administration of other types of doses than those injected from syringes. For example, it is possible that the stand is fitted for dosage  
15 units containing other types of medical doses, for example ampoules.

Figures 10 and 11 show some further embodiments. In Fig. 10, an injection pen is equipped with an indicating device with a lid to be turned away from the top of the push-button. The movement of turning  
20 the lid can be detected with a detector means, to register a dose as administered. Figure 11 shows a simple housing for one injection pen, in which the pen can be inserted and pulled out to administer a dose. This housing can operate in a corresponding way as a stand intended for several pens, with the only difference that it is used for monitoring  
25 one dosage unit only, and the functions of the panel are integrated in the housing.

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Furthermore, in connection with all the devices it is possible to use a locking function after the administration of the dose is registered. Thus,  
30 the device is equipped with a latch that prevents the preparative measures for the administration, such as a switch or latch in the stand or in the housing, to prevent the turning of the lid shown in Fig. 10 or the removal of the injection pen from the stand or housing. This locking can be on for a certain precautionary time, which can start from the registration of an event of administration or end at a certain moment of  
35 time, e.g. as long as the predetermined allowance time (standby time) of the next administration starts or for a shorter time, e.g. until the end of the predetermined standby time. In the following, these possibilities

will be described with reference to Fig. 9. In the stand 2, the injection pens are intended to be placed, the ends with a pocket clip foremost, into their compartments 10, which have a shaped space, such as a widened portion made at the side of the recess for this purpose. In connection with each space, there is a latch 18 which in the locking position projects out above the pocket clip and prevents the pulling out of the injection pen. The latch 18 is activated when the pen is inserted back and the administration of the dose is registered. A precautionary time can be arranged with any of the principles mentioned above. The latch is arranged to be opened at the latest when the standby time of the injection pen in question starts, i.e. when it is allowed to administer a dose from the pen. The latch operates preferably in such a way that energy must be brought to it to keep it in the locking position and in the state without energy it will be open, for example a magnetic latch which, upon switching off of the current, is withdrawn by the effect of a spring to the open position. Thus, by turning off the current, the pen can be removed from the stand, if necessary, the settings being stored in the memory.

The indicating device, particularly one to be attached to an injection pen, does not necessarily need to have an alarm and remind function, but it can be intended only to register the event of administration, for example in the case of a dose which is to be taken in connection with having a meal and which has no definite time of the day. On the other hand, in connection with such an effective insulin, it is particularly important to prevent a double dosage.

The device can be implemented with normal electronic components, such as various sensors, sound and light indicators, a microprocessor, a timer, and a memory which is preferably a memory retaining its information in spite of a failure in the supply of current. These means are functionally coupled to each other to implement the functions of the device. The electronics of the device is, in its simplest form, arranged to register an administered dose, and the registration can, in its simplest form, be such that information about the event of administration is left in the device 2 without data on the quantity of the dose. Also, it is feasible that the device in connection with the injection pen is equipped with a function that indicates the quantity of the dose, wherein the detector

means must be capable of measuring the extent of the forward movement of the piston.

5 The indicating device 2 to be fixed to an injection pen can be attached to it in several ways. If the injection pen in question is intended for permanent use, the device can be equipped with fixing screws pressed against the surface of the pen, or the device 2 can be attached from the side, wherein it has a turnable or loose fixing plate which is tightened against the device so that the pen is clamped in between. Also, the  
10 device 2 can be pushed around the pen in the longitudinal direction of the pen and fixed with a quick coupling, e.g. with a rotatable quick coupling acting by the pressing principle placed in the device 2 at the end proximal to the tip of the injection pen. This is suitable particularly for disposable pens which are discarded when the insulin container is  
15 empty and to which the device 2 should be easily attachable. The device to be fixed to the injection pen may be provided with a rechargeable battery instead of a disposable battery. The battery can be placed with the injection pen in the charging stand. It can also be connected by means of a cable to a special portable power supply, and  
20 via the same cable it can be connected to a sound signalling apparatus with a good output capacity. The cable can be connected to the device 2 with a plug. The battery of the device 2 serves thus as reserve and produces the current required by the device if no separate battery is connected.

25 The design of the indicating device 2 intended for several dosage units 1 can be different than that presented above. The dosage units 1 are presented above as being placed in an upright position, but they can also be in a inclined or in a horizontal position. In addition to light and  
30 sound signals, the device may be provided with additional displays, such as close to each dosage unit 1 a numerical display showing the quantity of the dose and/or a numerical display showing the time of administration. The readings of the additional displays can naturally be  
35 changable.

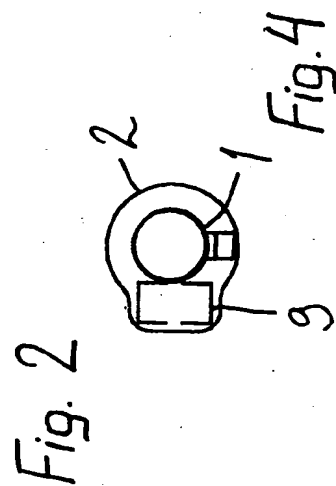
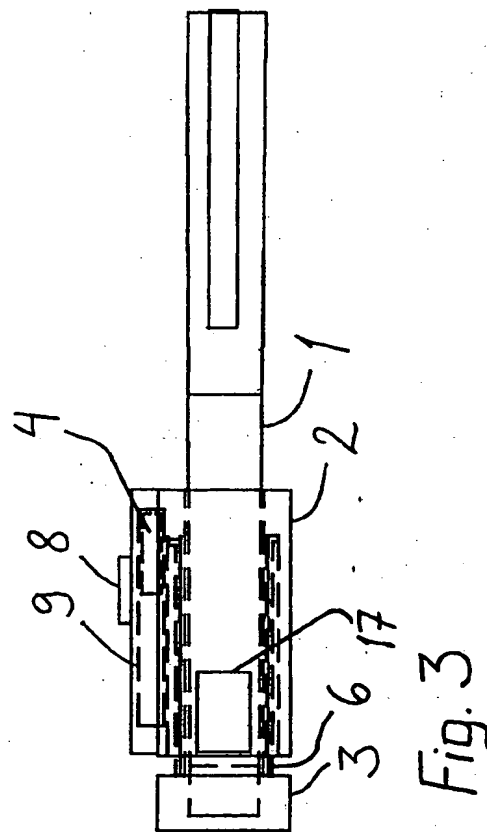
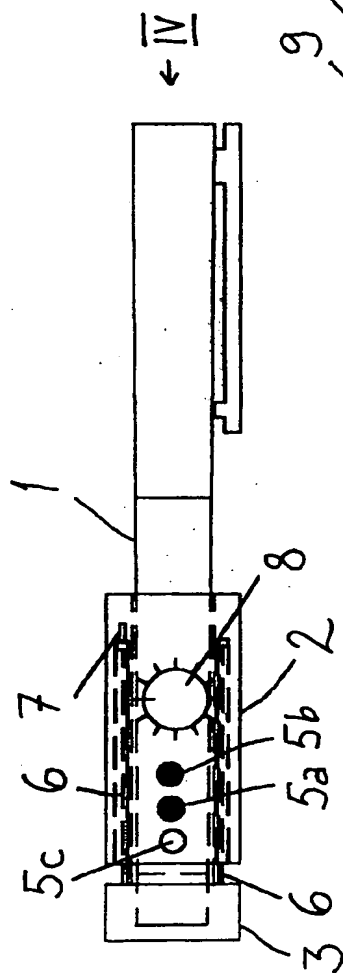
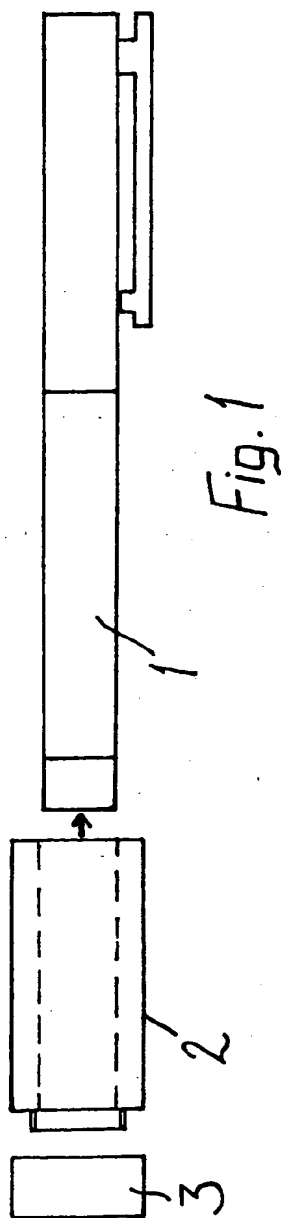
Claims:

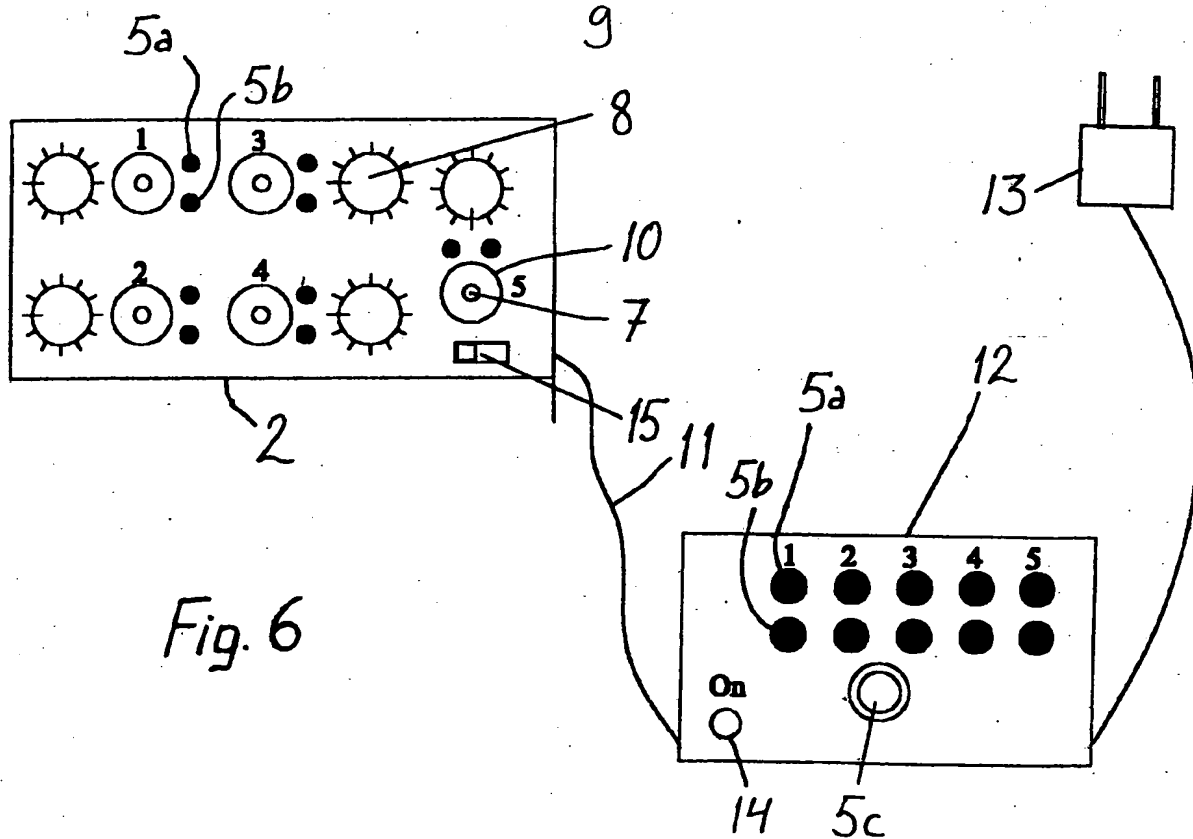
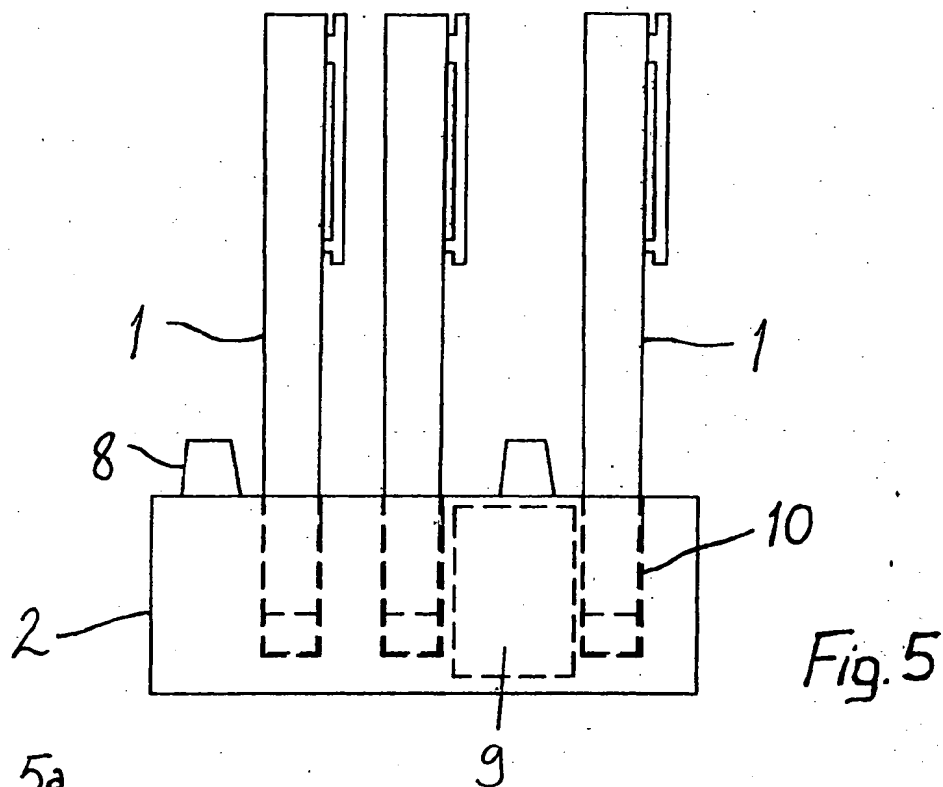
1. A device for indicating an event of administration, with an indicator for registering an event of administration of a usually regularly administrable medicament, **characterized** in that the indicating device (2) comprises a detector means (7) which is arranged to detect the mechanical movement of a medicament dosage unit (1) taking place in connection with an event of administration and the indicating device comprises a registration means which is arranged to register information about this in the indicating device (2).
2. The device according to claim 1, **characterized** in that it is a separate unit which can be attached to the medicament dosage unit (1) or in which the medicament dosage unit (1) can be placed.
3. The device according to claim 1 or 2, **characterized** in that it comprises an indicator (5b) which is arranged to give a warning if information about the event of administering a dose is registered and, within a certain precautionary time, the detector means (7) detects the mechanical movement related to a preparative measure for the administration.
4. The device according to any of the preceding claims, **characterized** in that it comprises an indicator (5b) which is arranged to indicate visually continuously for at least a certain time that information about the administration of a dose is registered.
5. The device according to any of the preceding claims, **characterized** in that it comprises an indicator (5a) which is arranged to give at determined intervals an alarm to indicate a time to administer a medicament.
6. The device according to any of the preceding claims, **characterized** in that the detector means (7) is arranged to detect the movement of a part in the dosage unit (1), such as a piston or a push-button or a part kinetically coupled thereto.

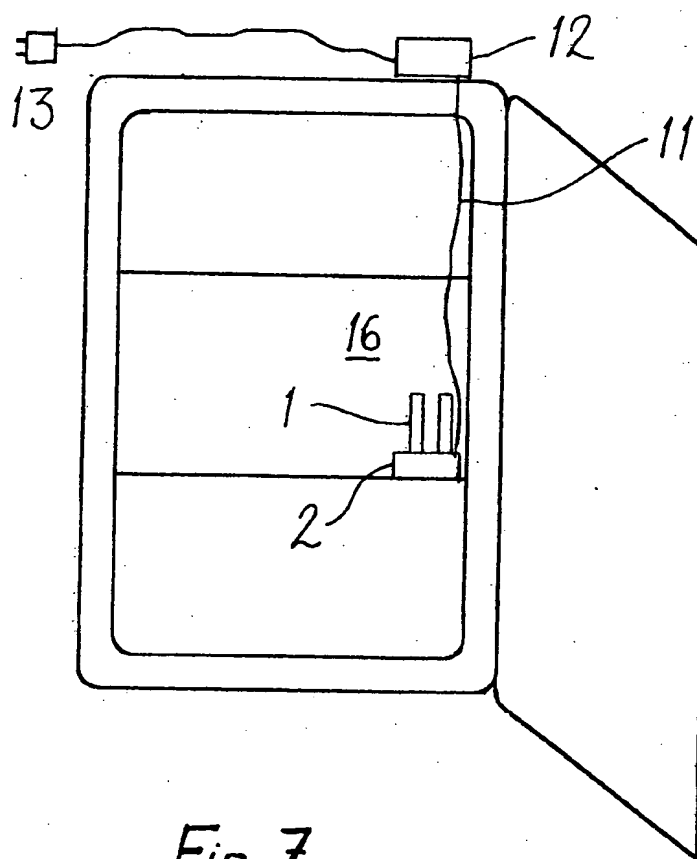


7. The device according to any of the preceding claims 1 to 5, **characterized** in that the detector means (7) is arranged to detect the movement of a part in the indicating device (2) related to a preparative measure for the administration, such as the transfer of a part covering a push-button or the like to set free the press or the like.
8. The device according to any of the preceding claims 2 to 5, **characterized** in that the indicating device (2) comprises a space for placing the dosage unit (1), the indicating device (2) and the dosage unit are removable from each other in connection with an event of administration, and the detector means (7) is arranged to detect the removal of the dosage unit (1) and the indicating device from each other.
9. The device according to claim 8, **characterized** in that the indicating device (2) is a stand comprising several locations, such as recesses (10) for dosage units (1), and several detector means (7) in the stand, allotted respectively to each dosage unit (1), are arranged to detect the removal of the respective dosage unit (1) from its location.
10. The device according to claim 9, **characterized** in that it comprises in the stand or in an indicator panel (12) connected to the stand, an indicator (5a) for each dosage unit (1), programmed to give an alarm related to the respective dosage unit.
11. The device according to any of the preceding claims, **characterized** in that it comprises an indicator pair (5a, 5b), of which the first indicator (5a) is arranged to indicate when it is time to administer a dose from the dosage unit (1), and the second indicator (5b) is arranged to give a warning or to indicate continuously for at least a certain time that a dose has been administered from the dosage unit (1).
12. The device according to claim 9, 10 or 11, **characterized** in that it comprises an alarm device which is arranged to trigger an alarm if the dosage unit (1) is not removed from its location at a predetermined time.

13. The device according to claim 12, **characterized** in that the alarm is arranged to trigger an alarm in the case that two dosage units (1) have not been removed from their locations at predetermined times.
- 5 14. The device according to claim 12 or 13, **characterized** in that the alarm device is arranged to trigger a remote alarm via a telecommunications line.
- 10 15. The device according to any of the preceding claims, **characterized** in that the device comprises a locking means which is arranged to lock the dosage unit (1) and the indicating device (2) to each other or the movable part of the indicating device (2) to be immovable, after the event of administration has been detected.
- 15 16. The device according to any of the preceding claims, **characterized** in that the dosage unit (1) for a medicament is a syringe or an injection pen for injectable doses, such as insulin doses.
- 20 17. A method for indicating an event of administration, in which an event of administration of a usually regularly administrable medicament is registered from a dosage unit (1), **characterized** in that the dosage unit (1) is equipped with a separate, detachable indicating device (2), and when administering the dose, a specific detector means (7) included in the indicating device (2) is used to detect the mechanical
- 25 movement of the dosage unit (1) related to the administration of the dose in the body or related to preparative measures for the administration, and the event is automatically registered from the detector means (7) in a memory in the indicator means (2).
- 30 18. The method according to claim 17, **characterized** in that it is used for monitoring the administration of doses to be administered from different dosage units (1) according to a certain regimen, wherein the use of each dosage unit (1) is registered automatically in the memory of the indicating device (2).
- 35 19. The method according to claim 17 or 18, **characterized** in that it is used for monitoring the administration of insulin doses to be administered at determined times from dosage units (1) containing insulin.





*Fig. 7*

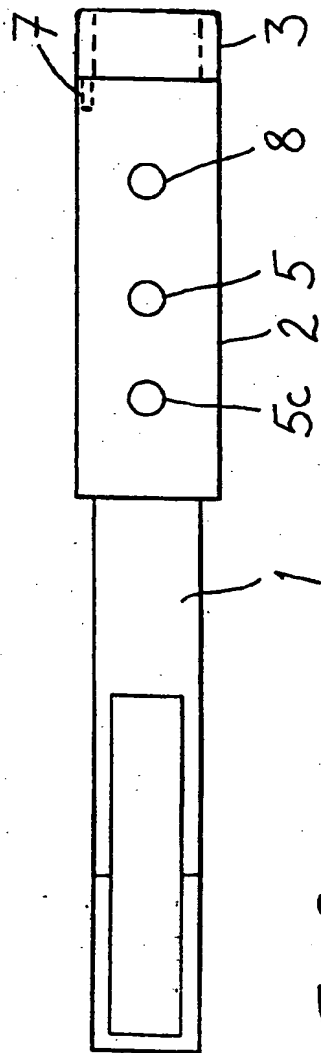


Fig. 8

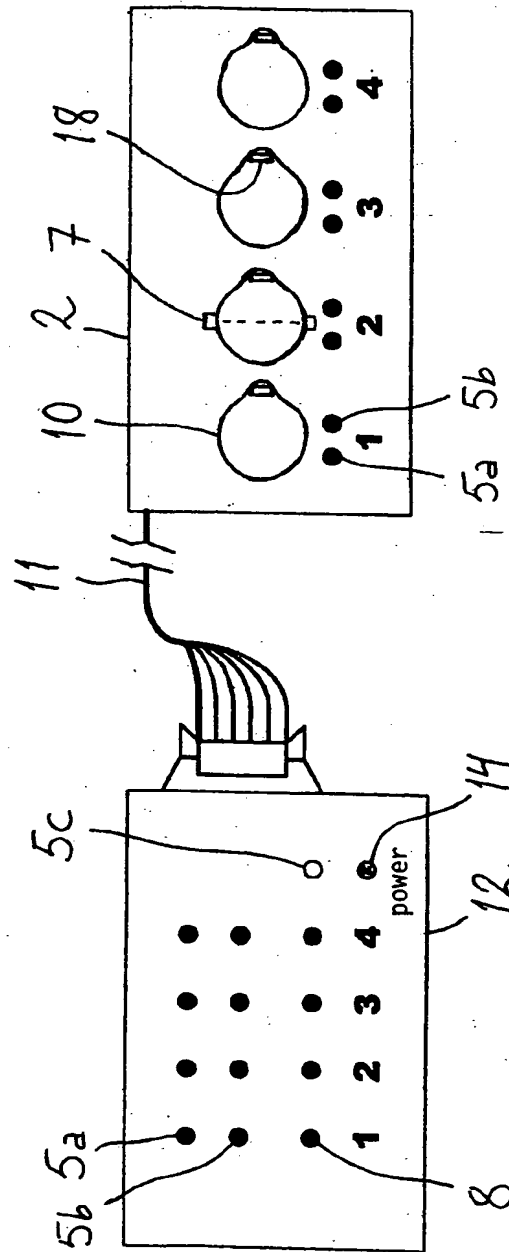


Fig. 9

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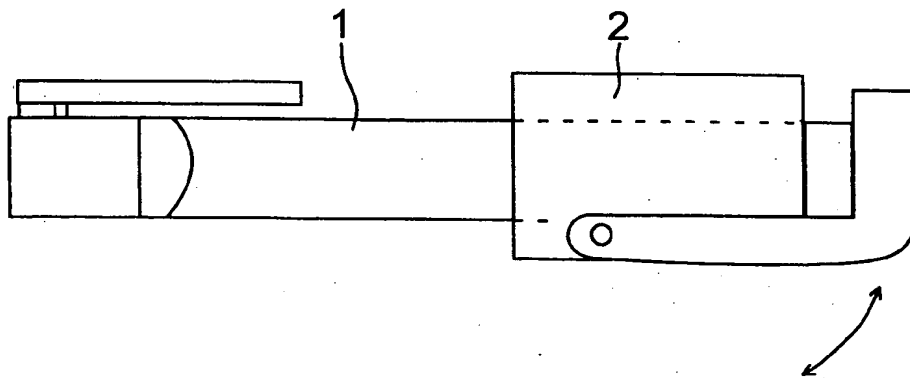


Fig. 10

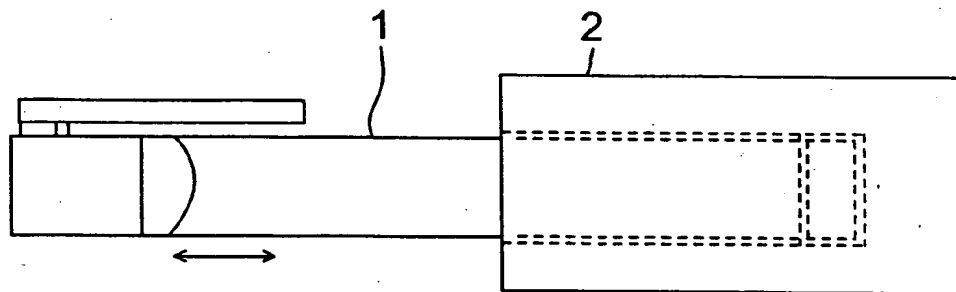


Fig. 11

## INTERNATIONAL SEARCH REPORT

International application No.

PCT/FI 99/00154

## A. CLASSIFICATION OF SUBJECT MATTER

IPC6: A61J 7/04

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC6: A61J

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,N0 classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5645534 A (CHANOCH), 8 July 1997 (08.07.97) --	1-7,15,16, 17,19
X	US 5593390 A (CASTELLANO ET AL), 14 January 1997 (14.01.97), figures 1-26, claims 1-44 --	1-7,15,16, 17,19
X	GB 2306707 A (TIMOTHY GEORGE HENSON), 7 May 1997 (07.05.97), figures 1-5, claims 1-19 --	1-7,15,17
X	WO 9313502 A1 (VITAFIT INTERNATIONAL, INC.), 8 July 1993 (08.07.93), figures 1-9, claims 1-12 --	1-7,15,17

☒ Further documents are listed in the continuation of Box C.☒ See patent family annex.

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Date of the actual completion of the international search

19 May 1999

Date of mailing of the international search report

07 -06- 1999

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PCT/FI 99/00154

## C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5200891 A (KEHR ET AL), 6 April 1993 (06.04.93), figures 1-15, claims 1-19  -- -----	1-7, 15, 17

**INTERNATIONAL SEARCH REPORT**

Information on patent family members

03/05/99

International application No.

PCT/FI 99/00154

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5645534 A	08/07/97	CA 2151001 A EP 0688572 A JP 2753462 B JP 8010326 A	25/12/95 27/12/95 20/05/98 16/01/96
US 5593390 A	14/01/97	AU 1939395 A EP 0749332 A EP 0777123 A JP 10504729 T WO 9524233 A US 5728074 A US 5536249 A	25/09/95 27/12/96 04/06/97 12/05/98 14/09/95 17/03/98 16/07/96
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WO 9313502 A1	08/07/93	AU 3419593 A US 5289157 A	28/07/93 22/02/94
US 5200891 A	06/04/93	US 5642731 A US 5752235 A	01/07/97 12/05/98

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